Clenil® 0.8 mg/2 ml vial suspension for nebulisation for Aerosol

beclomethasone dipropionate

Monodose vials (2ml) for aerosol therapy

COMPOSITION
100 ml of sterile suspension contain:
Active Ingredient: Beclomethasone dipropionate 0.040 g.
Excipients: Sodium chloride; Polysorbate 20; Sorbitan monolaurate; Water for injections.

PHARMACO –THERAPEUTIC CATEGORY
Antiasthmatic corticosteroid for aerosol.

THERAPEUTIC INDICATIONS
Control of the development of asthmatic diseases and bronchostenotic conditions. Allergic or vasomotor rhinitis, inflammatory and allergic affections of the nasal cavities and of the rhino-pharyngeal tract.

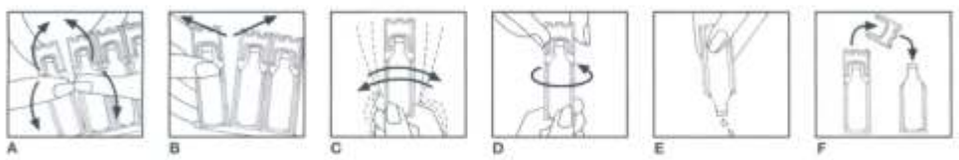
CONTRAINDICATIONS
Active or latent viral and tubercular infections. Individual hypersensitivity to any of the components. Contraindicated during pregnancy and lactation (see Special Warnings).

PRECAUTIONS FOR USE
Infections of the nasal cavities or of paranasal sinuses should be treated with a suitable therapy, but do not represent specific contraindications to the use of CLENIL. Though CLENIL is able to control in most of cases seasonal allergic rhinitis, an abnormally high stimulation of allergens could require a suitable supplemental therapy. Patients switching from continuos treatment with steroids by systemic route to therapy with CLENIL must be cautious if there is any reason to suppose that the adrenal function is impaired. However, at the beginning, CLENIL should be administered without discontinuing the systemic treatment, which should then be gradually reduced while keeping the patients under regular control (periodical tests of the cortico-adrenal functions, in particular, should be performed) and modifying the dosage of CLENIL according to the obtained results. During periods of stress or severe asthmatic crisis, patients undergoing this switch should have supplemental treatment with systemic steroids. Therapy with CLENIL has not shown any reduction of plasma cortisol concentrations, so far. This reduction was only observed in patients receiving double the maximum advised dose of beclomethasone dipropionate administrated by pressurised aerosol. Patients should be kept under strict medical control during prolonged treatments, in order to avoid impairment of the adrenal function, possibly occurring following excessive use of the product. These cases are unlikely to occur, but in case treatment should be discontinued and the patients immediately protected against the effects of the adrenal suppression, by a suitable systemic therapy.

SPECIAL WARNINGS
Pregnancy and Lactation: The drug must not be administered during the first three months of pregnancy. In the remaining period, during lactation and first infancy CLENIL should be given only in case of real need and under direct medical control.

POSOLOGY, METHOD AND FREQUENCY OF ADMINISTRATION
Adults: 1 monodose vial once, twice daily.
Children: half content of a monodose vial once, twice daily.
On the vial a mark corresponding to half a dose is reported.
Shake well before use.

Instruction for use of monodose vial
Follow the indication below to use the monodose vial:
1) Bend the vial in the two directions (see fig. A)
2) Separate the monodose vial from the strip at the top and then in the central part of the vial (see fig. B)
3) Shake well the vial in order to homogenise the suspension. Repeat this operation until the suspension content is homogeneously mixed up (see fig. C)
4) Open the vial by rotating the twist-off stopper (see fig. D)
5) Gently squeeze the vial to drop the drug at the prescribed dose into the nebuliser chamber, by moderately pressing the vial walls (see fig. E)
6) If only half dose is required, reinsert the cap upside down by pushing it onto the vial (see fig. F). The vial closed in this way must be stored at 2°C to 8°C (in the refrigerator) and the residual quantity has to be used within 12 hours after first opening.



UNDESIRABLE EFFECTS
Following administration of beclomethasone dipropionate by aerosol route, in some patients candidiasis might occur in mouth or throat. Patients with anamnestic or laboratory data indicating a previous infection could easily develop this complication. The incidence of candidiasis seems to be related to the administered dose. This affection generally responds to a suitable topical anti-mycotic therapy without discontinuing the treatment with beclomethasone dipropionate. The onset of these mycotic infections can be markedly reduced by regular rinsing the mouth after each application.
In patients with very sensitive airways, the use of the drug could give rise to cough and hoarseness.

The occurrence of undesirable effects is reduced if instructions are strictly followed. Inform your doctor or pharmacist, should any undesirable effects not described in this leaflet occur.

SHELF LIFE AND SPECIAL PRECAUTIONS FOR STORAGE
Store the product vertically, as described on the outer pack.
Expiry date: see outer pack; this date refers to the correctly stored and unopened package. Monodose vials can be stored out of the protecting strip up to 3 months.
If only half dose is used, the residual quantity of the vial has to be stored at 2°C to 8°C (in the refrigerator) and must be used within 12 hours.

Warning: Do not use beyond the expiry date reported on the outer pack.
Keep out of the reach of children
Last revision: March 2003

Chiesi

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کلینل ایروسول نیبولائزر سسپنشن

بیکلومیتھازون ڈائی پروپیونیٹ

اجزائے ترکیبی اور وضاحت:

100 ملی لیٹر سسپنشن میں بیکلومیتھازون ڈائی پروپیونیٹ 0.040 گرام بطور عامل جز شامل ہے۔

علامات:

دمہ کی بیماری اور سانس کی نالیوں کی سوزش/سوجن کو قابو کرنے کیلئے۔

ممانعت برائے علاج:

ایسے مریض جن کو پھیپھڑوں کی عمومی یا شدید ٹی بی ہو۔ ایسے مریض جن کو دوا میں موجود کسی جز سے زود حسی (الرجی) ہو۔ دودھ پلانے والی اور حاملہ خواتین اپنے معالج کی زیر نگرانی صرف انتہائی ضرورت کے تحت دوا استعمال کر سکتی ہیں۔

خوراک:

بڑوں کیلئے: ایک وائل (Vial) دن میں ایک سے دو مرتبہ۔

بچوں کیلئے: ایک وائل (Vial) کے نصف اجزا دن میں ایک سے دو مرتبہ ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔ آدھی خوراک استعمال کرنے کیلئے ہر وائل (Vial) کے اوپر نشان لگے ہوئے ہیں جو وائل (Vial) پر باآسانی دیکھے جا سکتے ہیں۔

کلینل ایروسول نیبولائزر سسپنشن وائل (Vial) کو درست استعمال کرنے کے لئے ہدایات:

مونوڈوز وائل (Monodose Vial) کو استعمال کرنے کے لئے نیچے دی گئی ہدایات پر عمل کریں۔

۔ایک وائل (Vial) کو دونوں اطراف بار بار موڑیں (تصویر A دیکھیں)۔

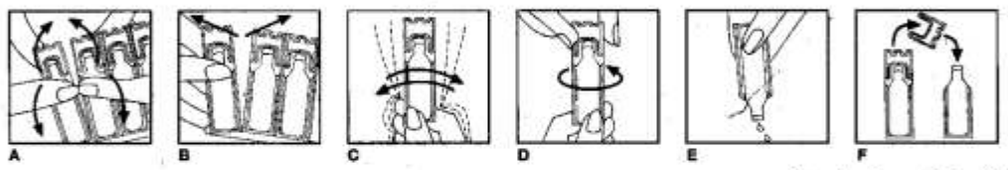
۔ایک وائل (Vial) کو پٹی سے علیحدہ کرنے کے لئے پہلے اوپر اور پھر بیچ سے علیحدہ کریں۔ (تصویر B دیکھیں)۔

۔استعمال سے پہلے وائل (Vial) کو اچھی طرح ہلائیں۔ اس عمل کو دوہراتے رہیں حتیٰ کہ سسپنشن کے ذرات یکساں طور پر حل ہو جائیں (تصویر C دیکھیں)۔

۔وائل (Vial) کے ڈھکن کو گھماتے ہوئے کھولیں (تصویر D دیکھیں)۔

۔علیحدہ کی ہوئی وائل (Vial) کے اوپر والے حصے کو نیچے کی طرف کر کے دبائیں تاکہ کلینل ایروسول کا محلول نیبولائزر کے کپ (Chamber) میں ڈالا جا سکے (تصویر E دیکھیں)۔

۔اگر صرف آدھی خوراک استعمال کرنا مقصود ہو تو وائل (Vial) کے ڈھکن کو الٹا کر دوبارہ بند کر دیں (تصویر F دیکھیں)۔ بچنے والی خوراک کو 12 گھنٹے کے اندر استعمال کر لیں۔



خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت کی جائے۔

تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

دوا کو 25°C سے کم درجہ حرارت پر، نمی اور روشنی سے محفوظ رکھیں۔

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